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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT

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3738

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 1 and 3, it is not understood how the new limitation in claims 1 and 3 that the hinge points “define an axis of rotation between adjacent links”.... facilitate relative rotation of said links. Since it is not understood how the links are considered to rotate, this is indefinite. Rotate is defined to permit a complete turn about a center point. The links of the claimed invention are not attached by any type of ball joint which is structure that permits rotation, and thus to define the invention such that it permits rotation is indefinite. The Examiner understands there is pivoting or bending of links, just like the prior art, but the structure is clearly not designed to permit complete rotation.

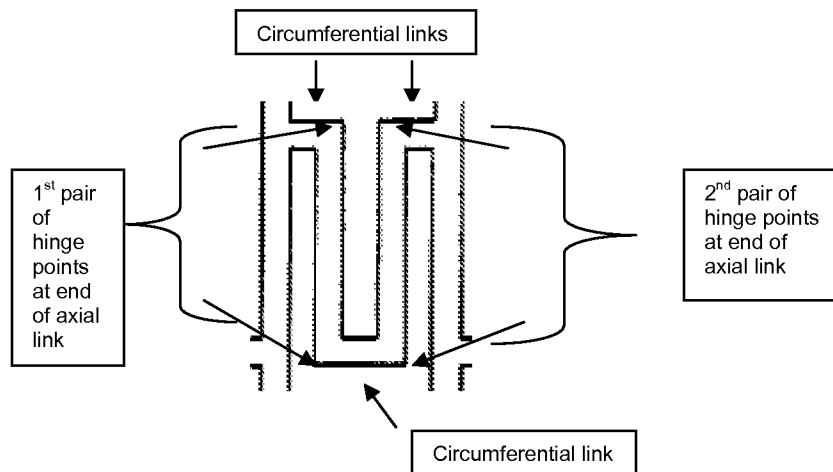
### ***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Israel et al. (5733303). Fig. 2 shows a stent with circumferentially spaced longitudinal struts **22**

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interconnected by linkages having a pair of hinge points that are angularly disposed and permit radial expansion and spaced apart at predefined locations.



The corners of the links form hinge points, which are fully capable of deforming upon radial expansion. Please note that in order for functional recitations to be given patentable weight, a functional limitation must be supported by recitation in the claim of sufficient structure to warrant the presence of the functional language. *In re Fuller*, 1929 C.D. 388 O.G. 279. There is no structure recited in the claim other than hinge points and thus, Israel discloses (col. 3, lines 38-40,43-45,48,49) the hinges allow for bending or deformation, which thus have "zones of relative weakness" along these links since all materials have the capability of being deformed. Israel discloses the struts inhibit *relative* foreshortening of the stent body, col. 1, line 53, col. 5, lines 13-65. There is bending or pivoting that occurs during expansion that can be considered "relative rotation".

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Israel et al. '303 in view of Orth et al. (5591197). Israel et al. is explained supra. However, Israel fails to disclose the hinge point *zones* of relative weakness are of a reduced cross-sectional profile. Orth et al. teach (Figs. 3A and 4A) a *connector or link* with notches or reduced cross-sectional areas to provide a weakened area, col. 6, lines 51-54. It would have been obvious to one of ordinary skill in the art to use a reduced cross-sectional in a link area as taught by Orth in the stent of Israel in order to impart greater flexibility.

Claims 3,5-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Israel et al. '303 in view of Hickie et al. (5139480). Israel is explained supra. However, Israel et al. fail to disclose the linkages having intersections of the axial and circumferential links forming nodes with greater cross-sections than the central portion of the adjacent link. Hickie et al. teach (Figs. 1A-1D) that stents can have links of various length and have nodes at the ends of the link where it intersects with another or linking material. It can also be seen that there is tapering of the links at the ends to the central section. Hickie also teaches that reduced cross-sections can be used in any direction with respect to the axis of the stent body, col. 5, lines 1-5. It would have been obvious to one of ordinary skill in the art to incorporate reduced cross-section linkages as taught by Hickie et al. in the stent of Israel et al. such that enhances the bendability

and reduces the stresses during expansion and would yield predictable results from doing so.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Israel et al. '303 in view of Hickie et al. '480 as applied to claim 3 above, and further in view of MacGregor (4994071). Israel as modified by Hickie is explained as before. However, Israel in view of Hickie fail to disclose all the linkages being unidirectionally facing. MacGregor teaches (Fig. 1) that all the linkages 12 connecting struts are unidirectionally facing since an axis along the length will have each of the linkages along that axis facing in the same direction. It would have been obvious to one of ordinary skill in the art to place linkages in a unidirectional way as taught by MacGregor in the stent of Israel as modified by Hickie since doing so produces predictable results of a more uniform expansion.

### ***Response to Arguments***

Applicant's arguments filed 5/13/08 have been fully considered but they are not persuasive. First it should be noted that independent claim 1 defines the links are designed to pivot or bend at a **point**. A point is an arbitrary location on an element and does not define any particular structure. Applicant uses the term "hinge point" in an attempt to impart some special structure. In response to applicant's argument that the reference (Israel) fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the "special structure" that permits "relative rotation" about an axis of rotation defined by reduced cross section) are not

recited in the rejected claim. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). There is no structure supporting applicant's functional language and thus Applicant fails to structurally define over Israel with respect to claim 1. Applicant argues that the claimed invention has "controlled" deformation of the linkages and the prior art Israel hinge points are expanded to become deformed in an uncontrolled fashion. While the Examiner appreciates the nice Exhibits submitted to show what Applicant means by "controlled", the Applicant provides no evidence that the prior art is not controlled. Limitations from drawings are not read into claims to define an invention and it cannot be said or alleged that prior art is any different from the claimed invention when the claims do not distinguish structurally from the prior art.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Orth provides a teaching to use the areas of weakness or reduced cross-section. Applicant proposes that this would be bad since the elements of Orth's stent project out and anchor the stent in the vessel wall. However, the stent should be secured in a vessel so it does not

migrate which is known to occur with some stents. Therefore, the Examiner is not persuaded.

Applicant argues the rejection of Israel and Hickie is not proper, alleging that Hickie does not teach the claimed hinge and refers to other illustrations of Hickie, however, not relied on by the Examiner. The Examiner notes that Hickie teaches (col. 3, lines 24,29-31,43) that different amounts of stresses can result in the structures illustrated. It can be deduced from the teaching that the optimal structure for linkages be of a design as illustrated such that it eliminates or reduces the stress to prevent breaking. Hickie did not state anywhere that such structures as illustrated in Figs. 1c,1d cannot be used and the Examiner suggested that these profiles are capable of being incorporated into Israel's structure to reduce the stress at the corners.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of



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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (9am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700  
/Brian E Pellegrino/  
Primary Examiner, Art Unit 3738